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 ( Not for submission under 37 CFR 1.99)

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| Application Number     | 10655889            |
| Filing Date            | 2003-09-04          |
| First Named Inventor   | Schmidt, Richard A. |
| Art Unit               | 1651                |
| Examiner Name          | Alremova, Vera      |
| Attorney Docket Number | 5662-1-PUS-1-1      |

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|                   | 1       | 5437291       |                        | 1995-06-01 | Pasricha, et al.                                |                                                                          |
|                   | 2       | 4932936       |                        | 1990-06-12 | Dykstra et al.                                  |                                                                          |
|                   | 3       | 5183462       |                        | 1993-02-02 | Borodic                                         |                                                                          |

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|                                      | 1       | 20050048084        |                        | 2005-03-03       | Schmidt, Richard A.                             |                                                                          |        |

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|                          | 1       | 6-183975                             | JP                        |                        | 1994-07-05       | LILLY CO ELI                                    | Abstract in English                                                      | <input type="checkbox"/> |

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|  |   |             |  |  |            |             |  |                          |
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|  | 2 | WO 95/17904 |  |  | 1995-07-06 | Aoki et al. |  | <input type="checkbox"/> |
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|                    | 1       | AMARENCO, Pour la pratique, Lae Revue du Praticien (Paris), 1995, 343-345, 45, FRANCE and abstract in English                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> |
|                    | 2       | ARAKI et al. Detrusor-Sphincter Dyssynergia with Special Reference to its Diagnosis and Treatment, J. Saitama Med. School, 1992, 23-27, Vol. 19, Department of Urology, Saitama Medical School, Moroyama, Iruma-gun, Saitama, JAPAN                                                                                                                                               | <input type="checkbox"/>            |
|                    | 3       | BULAU, Therapeutische Perspektiven mit Botulinumtoxin Type A., Neurologie und Rehabilitation, 1997, 55-56, GERMANY                                                                                                                                                                                                                                                                | <input type="checkbox"/>            |
|                    | 4       | DOGGWEILER et al., Botox-Induced Prostatic Involution, The Prostate, 1998, 44-50, Vol. 37, University of Colorado Health Science Center, Denver, CO, USA                                                                                                                                                                                                                          | <input type="checkbox"/>            |
|                    | 5       | DYKSTRA et al., Effects of Botulinum a Toxin on Detrusor-Sphincter Dyssynergia in Spinal Cord Injury Patients, J Urol, May 1998, 919-922, Vol. 159, Departments of Physical Medicine and Rehabilitation and Urologic Surgery, University of Minnesota Hospital and Clinic, Minneapolis Minnesota, USA                                                                             | <input type="checkbox"/>            |
|                    | 6       | FOWLER et al., Mytonic-Like EMG Activity of the Urethral Sphincter in Women with Urinary Retention and the Use of Botulinum Toxin to Treat this Disorder, Neurophysiologie Clinique, 1990, 19s, Vol. 20, Department of Uro-Neurology, National Hospital for Nervous Diseases, Queen Square and Urology Departments, The London Hospital and the Middlesex Hospital UNITED KINGDOM | <input type="checkbox"/>            |
|                    | 7       | FOWLER et al., Botulinum Toxin in the Treatment of Chronic Urinary Retention in Women, British Journal of Urology, 1992, 387-389, Vol. 70, British Journal of Urology, UNITED KINGDOM                                                                                                                                                                                             | <input type="checkbox"/>            |
|                    | 8       | MARIA et al., Relief by botulinum toxin of voiding dysfunction due to prostatitis, LANCET (North American Edition), 1998, 625, Vol. 352, Departments of Surgery, Urology and Neurology, Catholic University of Rome, Rome, USA                                                                                                                                                    | <input type="checkbox"/>            |

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|    |                                                                                                                                                                                                                                                                   |                          |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| 9  | HARRISON, Principles of Internal Medicine, 1987, 196-197, 11th Edition, McGraw-Hill Book Company, New York, New York, USA                                                                                                                                         | <input type="checkbox"/> |
| 10 | JANKOVIC, Botulinum toxin in movement disorders, Current Opinion in Neurology, 1994, 358-366, Vol. 7, Baylor College of Medicine, Houston, Texas, USA                                                                                                             | <input type="checkbox"/> |
| 11 | JANKOVIC, Therapeutic uses of Botulinum, The New England Journal of Medicine, 1991, 1186-1194, Vol. 324 No. 17, Department of Neurology, Baylor College of Medicine, Houston, Texas, USA                                                                          | <input type="checkbox"/> |
| 12 | KARP, et al., Therapeutic Effects of Botulinum Toxins, Handbook of Natural Toxins; Bacterial Toxins and Virulence Factors in Disease, 1995, 1-22, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland, USA | <input type="checkbox"/> |
| 13 | PUNCH, Gynaecological, and non-gynaecological, chronic pelvic pain, The Lancet, February 21, 1998, 607, Vol. 351, Department of OB/GYN, University of Michigan Medical Center, Women's Hospital, Ann Arbor, Michigan, USA                                         | <input type="checkbox"/> |
| 14 | STEINHARDT et al., Botulinum Toxin Novel Treatment for Dramatic Urethral Dilation Associated with Dysfunctional Voiding, The Journal of Urology, 1997, 190-191, Vol. 158, American Urological Association, Inc., St. Louis, Missouri, USA                         | <input type="checkbox"/> |
| 15 | ZWERGEL, et al. "Bladder Dysfunction in Disseminated Encephalomyelitis-Drug Therapy and Interventional Methods, Fortschritte Der Neurologie Psychiatrie, 1995, 495-503, Vol. 63, Neurologische Klinik der Universitat des Saarlandes, Homburg/Saar, GERMANY       | <input type="checkbox"/> |
| 16 | GRISE, PHILLIPPE, Affidavit, September 26, 2006                                                                                                                                                                                                                   | <input type="checkbox"/> |
| 17 | GROSSE, JOACHIM, Affidavit, September 25, 2006                                                                                                                                                                                                                    | <input type="checkbox"/> |
| 18 | CARL, STEFAN, Affidavit, September 26, 2006                                                                                                                                                                                                                       | <input type="checkbox"/> |
| 19 | E. Shapiro et al., "Quantifying the Smooth Muscle Content of the Prostate...", The Journal of Urology 147 (1992), pages 1167 to 1170                                                                                                                              | <input type="checkbox"/> |

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|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| 20 | G.E. Borodic and L.B. Pearce, "New Concepts in Botulinum Toxin Therapy", Drug Safety 11 (1994), pages145-152                                                                                                                                                                   | <input type="checkbox"/>            |
| 21 | Internet presentation on prostate disorders and the anatomy of the prostate/bladder:<br><a href="http://www.familydoctor.co.uk/htdocs/PROSTATE/PROSTATE_specimen.html">http://www.familydoctor.co.uk/htdocs/PROSTATE/PROSTATE_specimen.html</a> (printed on December 11, 2006) | <input type="checkbox"/>            |
| 22 | Internet presentation on prostatitis: <a href="http://www.urology-health.org/adult/index.cfm?cat=07&amp;topic=15">http://www.urology-health.org/adult/index.cfm?cat=07&amp;topic=15</a> (printed on December 11, 2006)                                                         | <input type="checkbox"/>            |
| 23 | Entry for "benigne Prostatahyperplasie" in Pschyrembel, klinisches Wörterbuch (257.Auflage, 1994)                                                                                                                                                                              | <input type="checkbox"/>            |
| 24 | Martinez Pinero et al., "Pelvic Plexus Denervation in Rats Causes Morphologic and Functional Changes of the Prostate", The Journal of Urology 150 (1993), pages 215-218                                                                                                        | <input type="checkbox"/>            |
| 25 | Amerencio, "Evaluation et Traitment des Dysfonctionnements Vesico-Sphinctériens Neurogènes" Annales d'Urologie 27 (1993) pages 313-320                                                                                                                                         | <input checked="" type="checkbox"/> |

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See attached certification statement.  
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|------------|------------------|---------------------|------------|
| Signature  | /Darla G. Yoerg/ | Date (YYYY-MM-DD)   | 2007-04-10 |
| Name/Print | Darla G. Yoerg   | Registration Number | 48053      |

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